# Complete Summary

## GUIDELINE TITLE

ACS guidelines for breast cancer screening: update 2003.

## BIBLIOGRAPHIC SOURCE(S)

Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP 3rd, Foster RS Jr, Hendrick E, Eyre HJ, Sener S. American Cancer Society guidelines for breast cancer screening: update 2003. CA Cancer J Clin 2003 May-Jun;53(3):141-69. [184 references] PubMed

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Breast cancer

### GUIDELINE CATEGORY

Diagnosis
Screening

### CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Preventive Medicine
Surgery

### INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

### GUIDELINE OBJECTIVE(S)

To review the existing American Cancer Society (ACS) guidelines for the early detection of breast cancer based on evidence that has accumulated since the last revision in 1997

### TARGET POPULATION

Women aged 40 years or older

### INTERVENTIONS AND PRACTICES CONSIDERED

1. Annual mammography beginning at age 40
2. Clinical breast examination (CBE)
3. Breast self-examination (BSE)
4. Screening of older women with comorbid conditions
5. Screening of women at high risk
6. Additional screening modalities such as ultrasound and magnetic resonance imaging (MRI) were considered but not recommended

### MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality due to breast cancer in women aged 40 years and older
- Clinical performance characteristics of screening tests (sensitivity, specificity)

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

During the current guideline review, literature related to breast cancer screening published between January 1997 and September 2002, including new screening tests, was identified using MEDLINE (National Library of Medicine), bibliographies of identified articles, personal files of panel members, and unpublished manuscripts.

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of evidence rating scheme for rating potential new imaging technologies for breast cancer detection

A. Strong clinical evidence for effectiveness in screening; technology is routinely used for screening
B. Some clinical evidence for effectiveness or equivalence to screen-film mammography for screening
C. Preclinical data suggest possible promise, but clinical data are sparse or nonexistent; more study is needed
D. Clinical evidence indicates that modality is ineffective as a screening tool
E. Technology is not at the stage that data are available

## METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review
Review of Published Meta-Analyses

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

In 2002, the American Cancer Society (ACS) convened an expert panel to review the existing early detection guidelines based on evidence that has accumulated since the last revision. The panel was divided into work groups to review recent evidence and develop recommendations regarding: (1) mammography; (2) physical examination; (3) screening of older women and women with comorbid conditions; (4) screening high-risk women; and (5) screening with new technologies.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert panel members reviewed articles using specified criteria and discussed them during a series of conference calls. Each group developed recommendations, rationale, and evidence summaries, and reviewed the summaries developed by the other work groups prior to a September 2002 workshop. When evidence was insufficient or lacking the final recommendations incorporated the expert opinions of the panel members. During the conference calls and workshop, consensus was reached on the key issues within the guideline recommendations. Following the workshop, ACS Breast Cancer Advisory Group members deliberated over the guideline modifications.

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Each work group member and workshop attendee was given the opportunity to review the draft of this manuscript. Numerous professional, advocacy, and governmental organizations also were invited to review the draft guidelines.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### Summary Recommendation

The American Cancer Society recommendations for breast cancer screening are presented below in abbreviated form. Readers should refer to the original full text guideline document to see the complete recommendations, along with the rationale and summary of the evidence.

#### Women at Average Risk

Begin mammography at age 40.

For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination, preferably at least

every three years. Asymptomatic women aged 40 and over should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.

Beginning in their 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly.

Women should have an opportunity to become informed about the benefits, limitations, and potential harms associated with regular screening.

#### Older Women

Screening decisions in older women should be individualized by considering the potential benefits and risks of mammography in the context of current health status and estimated life expectancy. As long as a woman is in reasonably good health and would be a candidate for treatment, she should continue to be screened with mammography.

#### Women at Increased Risk

Women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women of average risk, such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities other than mammography and physical examination, such as ultrasound or magnetic resonance imaging. However, the evidence currently available is insufficient to justify recommendations for any of these screening approaches.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The primary evidence supporting the recommendation for periodic screening for breast cancer with mammography derives from seven randomized controlled trials (RCTs).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Decreased breast cancer morbidity and mortality due to early detection.

- A meta-analysis of seven randomized controlled trials (RCTs) showed a 24% mortality reduction associated with an invitation to screening.
- Evidence from service screening (i.e., screening in the community setting) demonstrates that modern, organized screening programs with high rates of attendance can achieve breast cancer mortality reductions equal to or greater than those observed in RCTs. Evaluation of service screening is an important new development because it measures the value of modern mammography in the community and it measures the benefit of mammography screening to women who actually get screened.

## POTENTIAL HARMS

Limitations and harms of breast cancer screening include false negatives, false positives, over-treatment, and radiation.

### False Negatives/False Positives

False negatives can be attributed to inherent technological limitations of mammography, quality assurance failures, and human error; false positives also can be attributed to these factors as well as to heightened medical-legal concerns over the consequence of missed cancers. Further, in some instances, a patient´s desire for definitive findings in the presence of a low-suspicion lesion also contributes to false positives. The consequences of these errors include missed cancers, with potentially worse prognosis, as well as anxiety and harms associated with interventions for benign or nonobligate precursor lesions.

The evidence suggests that some women experience anxiety related to screening, and a greater percentage experience anxiety related to false-positive results, but for most women psychological distress is short-lived and does not have lasting consequences on either stress levels or likelihood of subsequent screening.

### Overtreatment

Since some ductal carcinoma in situ (DCIS) is not progressive, diagnostic evaluation and treatment of DCIS lesions that would not progress to invasive disease is a harm associated with screening, although the extent of harm is uncertain, as is how it might be avoided. Overtreatment of a progressive DCIS lesion that could be cured with less aggressive treatment also represents a harm, although it should not be attributed to screening.

### Radiation

Several studies have provided evidence for an increased risk of breast cancer after therapeutic radiation exposure or multiple exposures to diagnostic radiation. Overall risk from single and cumulative diagnostic exposures is small, but risk increases with the amount of exposure and with younger age at exposure. Thus, it is theoretically possible that cumulative radiation exposure associated with screening mammography increases the risk of breast cancer. It has also been hypothesized that some women at increased inherited risk for breast cancer may also have increased radiation sensitivity, which could increase their risk for radiation-induced breast cancer.

Women whose regular screening begins at an early age (e.g., age 30) may have a higher potential for radiation-induced cancers.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- Because the recommendations for women at increased risk for breast cancer were based on limited observational data, the decision regarding when to initiate screening should be based on shared decision-making, taking into consideration individual circumstances and preferences.
- The evidence supporting the value of CBE and BSE as methods of reducing breast cancer mortality is limited and mostly inferential, although there is no definitive prospective RCT evidence from which to draw conclusions about either exam. Thus, current recommendations rely on existing evidence, but also on expert opinion based on a recognition that population-based studies continue to show a relatively large proportion of self-detected cancers.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP 3rd, Foster RS Jr, Hendrick E, Eyre HJ, Sener S. American Cancer Society guidelines for breast cancer screening: update 2003. CA Cancer J Clin 2003 May-Jun;53(3):141-69. [184 references] PubMed

### ADAPTATION

Not applicable: Guideline was not adapted from another source.

## DATE RELEASED

1997 (revised 2003)

## GUIDELINE DEVELOPER(S)

American Cancer Society - Disease Specific Society

## SOURCE(S) OF FUNDING

American Cancer Society

## GUIDELINE COMMITTEE

High-Risk Work Group
Mammography Work Group
New Technologies Work Group
Physical Examination Work Group
Screening Older Women Work Group

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Runowicz receives speaking fees and research support from Cytyc Corporation (First Cyte Ductal Lavage). Dr. Rubinstein is on the speaker´s bureau for Myriad Genetic Laboratories, Inc. Dr. D´Orsi is a medical consultant to GE Medical Systems and R2 Technology, Inc. Dr. Feig is on the medical advisory board of R2 Technology, Inc., a company that sells a computer-aided detection device for mammography; he does not receive any financial remuneration or grant support from the company. Dr. Giger is a shareholder in R2 Technology, Inc.; she also has received unrestricted research support from the company in the past.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Leitch AM, Dodd GD, Costanza M, Linver M, Pressman P, McGinnis L, Smith RA. American Cancer Society guidelines for the early detection of breast cancer: update 1997. CA Cancer J Clin 1997 May-Jun;47(3):150-3.

Each year the American Cancer Society publishes a summary of existing recommendations for early cancer detection, including updates, and/or emerging issues that are relevant to screening for cancer.

## GUIDELINE AVAILABILITY

Electronic copies: Available from CA online, A Cancer Journal for Clinicians, a publication of the American Cancer Society:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the American Cancer Society, 1599 Clifton Rd NE, Atlanta, GA 30329; Web site: www.cancer.org.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on March 12, 1999. The information was verified by the guideline developer as of February 28, 2000. This summary was updated by ECRI on July 21, 2003. The information was verified by the guideline developer on August 13, 2003.

## COPYRIGHT STATEMENT



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